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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,852	12/06/2001	Nicholas J. Papadopoulos	REG 710-A-US	1613

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EXAMINER

HUNNICUTT, RACHEL KAPUST

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,852

Applicant(s)

PAPADOPOULOS ET AL.

Examiner

Rachel K. Hunnicutt

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 92-100 and 104-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92-100 and 104-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 011603, 012803
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicant's election without traverse of Group 1, encompassing claims 92-100 and 104-108 as drawn to SEQ ID NO: 15, in the reply filed on December 13, 2004 is acknowledged. Claims 101-103 and 109-131 are canceled. Claims 92-100 and 104-108 are pending and under consideration.

Specification

The use of the trademark BIACORE™ (p. 18), MATRIGEL™ (p. 18), SUPEROSE™ (p. 24), SUPERDEX™ (p. 39), MACVECTOR™ (p. 51), ENDOFREE™ (p. 66), HYCLONE™ (p. 66), and SEPHAROSE™ (p. 70) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (p. 30). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

Claims 92-94, 96-98, 100, and 104-108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule encoding a VEGF receptor Ig domain 2 upstream of a VEGF receptor Ig domain 3, does not reasonably provide enablement for a nucleic acid molecule encoding a VEGF receptor Ig domain 2 downstream of a VEGF receptor IG domain 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention; 2) state of the prior art; 3) relative skill of those in the art; 4) level of predictability in the art; 5) existence of working examples; 6) breadth of claims; 7) amount of direction or guidance by the inventor; and 8) quantity of experimentation needed to make and/or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims encompass nucleic acid molecules encoding fusion proteins. The fusion proteins comprise a VEGF receptor Ig domain 2, a VEGF receptor Ig domain 3, and a multimerizing component. The claims encompass fusion proteins wherein the different domains and multimerizing component may be in any order, yet applicants only provide working examples of fusion proteins with domain 2 upstream of domain 3, and the multimerizing domain is attached to the C-terminus of domain 3. Herley *et al.* teach that the minimal region of Flt-1 required for VEGF binding contains either Flt-1 domains 1 and 2 or Flt-1 domains 2 and 3 (1999, *Biochem. Biophys. Res. Comm.* 262(3): 731-738). Herley *et al.* teach that a chimeric receptor containing only domain 2 of Flt-1 bound VEGF very weakly (p. 735). The skilled artisan would not expect the claimed fusion proteins having domain 2 downstream of domain 3 to be functional. Moreover, the skilled artisan would not expect the claimed fusion proteins having the multimerizing domain separating domain 2 and domain 3 to be functional. One skilled in the art would only expect the claimed fusion proteins having domain 2 immediately upstream of domain 3 to be functional VEGF antagonists.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 92-95, 97-98, 100, and 104-108 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,100,071 (mailed to Applicant November 23, 2004). Claims 92-95, 97-98, and 100 encompass nucleic acid molecules encoding fusion proteins, wherein the fusion protein comprises an Ig domain 2 of Flt1, an Ig domain 3 of Flk1 or Flt4, and a multimerizing component. The multimerizing component may be an immunoglobulin domain such as the Fc domain of IgG or the heavy chain of IgG. Claims 104-108 are drawn to expression vectors and host-vector systems for producing a fusion protein. The '071 patent teaches fusion proteins comprising an immunoglobulin constant region, the Ig domain 2 of Flt1, and the Ig domain 3 of Flt4 (see columns 17, 18, and 27). The '071 patent teaches expression vectors host cells such as E. coli, and methods of producing fusion proteins (see columns 13 and 14). Thus, claims 92-95, 97-98, 100, and 104-108 are anticipated by the '071 patent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

~~A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to~~
overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 92-95, 97-100, 104, 105, and 108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 7,

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and 8 of copending Application No. 10/609775. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application 10/609775 teaches SEQ ID NO: 9 which is identical to SEQ ID NO: 15 of the current application. Application 10/609775 claims isolated nucleic acid molecules encoding fusion proteins comprising the Ig domain 2 of Flt-1 and the Ig domain 3 of Flk-1 or Flt-4 and a multimerizing component.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
3/17/05


JANET ANDRES
PRIMARY EXAMINER